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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,122	03/20/2004	Andreas M. Papas	YH-AquaE	8910
41546	7590	01/21/2009		
DONNA J. RUSSELL 1492 ANTHONY WAY MT. JULIET, TN 37122			EXAMINER SILVERMAN, ERIC E	
			ART UNIT 1618	PAPER NUMBER
			NOTIFICATION DATE 01/21/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/805,122	Applicant(s) PAPAS ET AL.	
	Examiner ERIC E. SILVERMAN	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 13-23 is/are pending in the application.
- 4a) Of the above claim(s) 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15, 22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/2008 has been entered.

Claims 1-11 and 13-23 are pending; claims 16-21 are withdrawn; claims 1-11, 13-15, 22, and 23 are treated on the merits. It is noted that applicants' most recent response at page 7 states that claims 1-11 and 16-23 are pending. This is believed to be a typographical error; claims 14 and 15 are not listed as cancelled on the listing of claims.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 5 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 5,824,638 to Burnside et al. This rejection is not maintained over claims 6, 8, 1, 11, 22, or 23.

Response to Arguments

Applicants' argument that Burnside teaches water in oil (W/O) emulsions, which are structurally distinct from oil in water (O/W) emulsions is persuasive. This rejection is not maintained over claims requiring an O/W emulsion. However, the persuasive

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argument does not apply to claims 1, 2, and 5 because those claims are generic to the form of the composition, and do not require an O/W emulsion.

Claims 1, 2, 5, 6, 7, 8, 10, 11, 22, and 23 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/29300 ("300").

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' argument is that the inclusion of surfactants such as Tween 80 in 300 changes the novel characteristics of the claimed invention, and thus such surfactants are excluded from the invention by the "consisting essentially of" language.

At the outset, it is understood that this argument only applied to the rejection over claims 1, 2, and 5; claims 6, 7, 8, 10, 11, 22, and 23 all use open-ended "comprising" language that allows for the inclusion of additional ingredients even if they fundamentally change the nature of the invention. As applicants' present no argument germane to claims 6, 7, 8, 10, 11, 22, and 23 the rejection over those claims must be maintained.

With regard to claims 1, 2, and 5, applicants aver that surfactants may irritate membranes, and conclude that the artisan would recognize that absence of surfactants and emulsifiers other than Vitamin E TPGS and linoleic acid is part of the novel nature of the invention. This argument fails for at least two reasons.

First, there is no evidence of record to support applicants' allegation that surfactants generally, or the surfactants of 300 specifically, are irritating to membranes. Applicants' arguments are not evidence.

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Second, even if there was evidence to support the allegation that surfactants generally, and the surfactants of 300 specifically, are irritating to membranes, the inventive is not designed for administration to membranes. The claimed composition is designed to be used as an oral dosage form (claim 22) or a topical dosage form (claim 23). Oral dosage forms are ingested, and not applied to membranes. Topical dosage forms are administered to the skin and hair, not to membranes. Nowhere does the application envision administration to membranes, nor are mucoadhesive, or similar membrane-related dosage forms, discussed. The term "membrane" does not appear in the specification. The inventors did not envision a dosage form for administration to membranes. There is nothing in the disclosure to indicate that the inventors had any interest in avoiding membrane irritation. Thus it cannot be said that avoiding irritating membranes by excluding additional surfactants is part of the novelty of the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11, 13-15, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,824,638 to Burnside et al in view of US 5,883,103 to Burnside et al, WO 99/89300, and Roy et al in EFBS Lett. 2002 October 23; 530 (1-3):17-23 for reasons of record and those discussed below.

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Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicants argue that the additional surfactants required by the prior art are excluded by the rejected claims. This argument was addressed above, and is inapplicable or unpersuasive here for the reasons previously discussed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618